

Application/Control No. 09/975,621
Art Unit: 3762

REMARKS

This amendment is responsive to the Office Action mailed June 4, 2003. Applicant herein amends the independent claims 35, 51 and 67 and dependent claims 37, 38, 43, 47, 53, 54, 59, 63, 69, 70, 75, and 79. Thus, claims 35-80 stand pending examination on the merits.

The amendments presented herein are intended to place the pending claims in condition for allowance, without requiring additional search and without raising new or additional issues. Said amendments were not earlier presented because the procedural posture of the application did not merit such amendments. A single prior art reference to Wilson et al. stands as the only reference applied to reject claims 35-80 and Applicants respectfully suggest that said rejections stand traversed following entry of the instant amendment.

Entry and favorable consideration of the amendments and remarks tendered herewith is earnestly solicited so that the claimed invention may pass to timely issuance as U.S. Letters Patent.

Objections to the Claims

In the Office Action, the Examiner objected to claims 35-80 because the term "memory" was recited without antecedent basis. Applicants herewith corrected the claims as required by the Examiner by employing "memory structure" with suitable antecedent basis throughout the pending claim set.

Claim Rejection Under 35 U.S.C. § 102

In the Office Action, the Examiner rejected claims 35, 37, 47, 49-51, 53, 63, 65-67, 69 and 80 under 35 U.S.C. § 102(e) as being anticipated by U.S. Pat. No. 5,908,392 issued to Wilson et al. ("Wilson"). According to the Examiner, Wilson states in the Abstract and at column 13 that the new snapshots overwrite the data in the circular buffers.

Application/Control No. 09/975,621
Art Unit: 3762

Applicants respectfully suggest that via amendment to the independent claims submitted herein, Wilson fails to anticipate the presently claimed invention. Applicants suggest that Wilson does not include every claim limitation of the independent claims and thus, the claims depending therefrom as well.

Accordingly, invalidity by anticipation requires that the four corners of a single, prior art document describe every element of the claimed invention, either expressly or inherently, such that a person of ordinary skill in the art could practice the invention without undue experimentation. See Atlas Powder Co. v. Irecos Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999); In re Paulsen, 30 F.3d 1475, 1479, 31 USPQ2d 1671, 1673 (Fed. Cir. 1994). Material not explicitly contained in the single, prior art document may still be considered for purposes of anticipation if that material is incorporated by reference into the document.

For example, Wilson only describes and depicts a pacemaker having electrodes "in contact with" the heart. The presently claimed invention is not so limited. That is, the presently claimed invention may be practiced without a pacemaker (or pulse generator) and does not require electrodes in contact with the heart. In fact, with reference to at least one embodiment of the present invention an implantable loop recorder (ILR) device is depicted and described.

In support of the foregoing, Applicants refer the Examiner to the single paragraph describing how the electrogram (EGM) used in Wilson is obtained:

A pacemaker 10 in accordance with this invention is shown in FIG. 1. The pacemaker 10 is coupled to a heart 12 by way of leads 14 and 16, the lead 14 having an electrode 18 which is in contact with one of the atria of the heart 12, and the lead 16 having an electrode 20 which is in contact with one of the ventricles. The lead 14 carries stimulating pulses to the electrode 18 from an atrial pulse generator 22, while the lead 16 carries stimulating pulses to the electrode 20 from a ventricular pulse generator 24. In addition, electrical signals from the atria are carried from the electrode 18, through the lead 14 to the input terminal of an atrial sense amplifier 26. Electrical signals from the ventricles are carried from the electrode 20, through the lead 16 to the input terminal of a ventricular sense amplifier 28. (col. 5, ll. 17-31; emphasis added.)

In contrast, independent claims 35, 51, and 67 of the presently claimed invention each recite a claim limitation not found expressly or inherently in Wilson; namely:

Application/Control No. 09/975,621
Art Unit: 3762

"wherein said electrogram signal is obtained via at least a pair of subcutaneous electrodes spaced from a heart."

Since claims 37, 47, 49-50, 53, 63, 65-66, 69 and 80 depend either directly or indirectly from independent claim 35, 51 or 67 they too are not anticipated by Wilson.

For the foregoing reasons, Applicants respectfully traverse the anticipation rejection based on Wilson.

In view of the differences identified above, Wilson clearly fails to anticipate the features set forth in claims 35, 37, 47, 49-51, 53, 63, 65-67, 69 and 80.

Claim Rejections Under 35 U.S.C. § 103

In the Office Action, the Examiner rejected claims 38-46, 54-62 and 70-78 under 35 U.S.C. § 103(a) as being unpatentable over Wilson.

According to the Examiner, Wilson discloses the claimed invention except for the steps, instructions or means for compressing ECG signals prior to recording, for recording noise trigger signals in the ECG data record, and for parsing and displaying waveforms and icons of the trigger and/or noise signals from the ECG signals. The Examiner posits that the foregoing would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the recording and storage system of Wilson to render the recited claims obvious.

Applicants hereby incorporate the remarks set forth above with respect to Wilson as if fully set forth herein. In addition, Applicants aver that the Examiner has failed to lodge a *prima facie* obvious rejection as required by current practice. In addition, Applicants suggest that the Examiner has improperly utilized hindsight in an attempt to render the claimed subject matter obvious. Especially in light of the amendments tendered herewith, Applicants suggest that Wilson fails to suggest, teach or motivate one of skill in the art to utilize electrodes disposed on surfaces of a device housing and/or medical electrical

Application/Control No. 09/975,621
Art Unit: 3762

leads having electrodes *not in contact with a heart* to capture EGM signals for processing.

Applicants note that independent claim 35 is allowable in light of Wilson for the reasons given above. Claims 36-50 depend, directly or indirectly, upon claim 35, and are therefore allowable as well. Likewise, claims 52-66 depend, directly or indirectly, upon claim 51 and are also allowable. Furthermore, claims 68-80 depend, directly or indirectly, upon claim 67 and are therefore also presently allowable.

In connection with combining references to support an assertion of obviousness, it is well established that the Examiner bears the burden of establishing a *prima facie* case of obviousness. In re Oetiker, 24 USPQ2d 1443, 1445 (Fed. Cir. 1992). In doing so, the Examiner must determine whether the prior art provides a "teaching or suggestion to one of ordinary skill in the art to make the changes that would produce" the claimed invention. In re Chu, 36 USPQ2d 1089, 1094 (Fed. Cir. 1995). A *prima facie* case of obviousness is established only when this burden is met.

The burden is still on the Examiner even when the Examiner relies upon a single reference. "Even when obviousness is based on a single prior art reference, there must be a showing of a suggestion or motivation to modify the teachings of that reference." In re Kotzab, 55 USPQ2d 1313, 1316-17 (Fed. Cir. 2000).

In the case of In re Lee, 61 USPQ2d 1430 (Fed. Cir. 2002), the Federal Circuit stated: "This factual question of motivation is material to patentability, and [can] not be resolved on subjective belief and unknown authority." *Id.* at 1434. Determination of patentability must be based on evidence, *id.* at 1434, and the

For at least these reasons, the Examiner has failed to establish a *prima facie* case for non-patentability of Applicant's claims 38-46 (and 54-52 and 70-78) under 35 U.S.C. § 103(a). Withdrawal of this ground of rejection is hereby earnestly and respectfully requested.

Application/Control No. 09/975,621
Art Unit: 3762

Allowable Subject Matter

Applicants thank the Examiner for indicating that pending claims 36, 48, 52, 64 and 68 stand objected to but allowable over the prior art of record. For the reasons given above, claims 35-80 are neither anticipated by Wilson nor obvious in light of Wilson, and are therefore allowable.

CONCLUSION

All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims. Please charge any additional fees or credit any overpayment to deposit account number 13-2546. The Examiner is invited to telephone the below-signed attorney to discuss this application.

Date:

11 Aug. 04

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